PATENT

Attorney Docket No.: 17882-706 Application Serial No. 08/895,936

Please amend the above-identified application as follows:

In the Claims:

Please cancel currently pending claims 1-20 and 22-35 without prejudice, and insert new claims 36-68 as follows:

36. A method of processing biopharmaceuticals comprising:

providing a container for receiving a medium, the medium comprising a biopharmaceutical product;

positioning a structure in said container;

coupling, at least partially, a first heat exchange member to an interior surface of said container;

coupling, at least partially, a second heat exchange member to said structure wherein a portion of said first heat exchange member is placed in close proximity to a portion of said second heat exchange member;

introducing the medium into the container; and

forming a thermal transfer bridge between the first and second heat exchange members, wherein the thermal transfer bridge conducts heat out of the medium.

- 37. A method as in claim 36 wherein:a heating or cooling device is coupled to and provides heating or cooling of said
- 38. A method as in claim 36 wherein:
 a heating or cooling device is coupled to and provides heating or cooling of said structure.

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container.

- 39. A method as in claim 36 wherein:
 - a heating or cooling device is coupled to and provides heating or cooling of said structure and said container.
- A method as in claim 36 wherein:
 there is a plurality of heat exchange members.
- 41. A method as in claim 36, further comprising:
 a removable liner configured to cover at least a portion of said first heat exchange member.
- 42. A method as in claim 36, further comprising:
 a removable liner configured to cover at least a portion of said second heat exchange member.
- 43. A method as in claim 36, further comprising:
 a removable liner configured to cover at least a portion of said first heat exchange member and said second heat exchange member.
- 44. A method as in claim 36 wherein:
 a volume of said container is in the range from about 1 liter to about 250 liters.
- 45. A method as in claim 36 wherein:

 a volume of said container is in the range from about 250 liters to about 10,000 liters.
- 46. A method as in claim 36 wherein:

 a distance between said distal end of said first heat exchange member and a
 distal end of said second heat exchange member is a non-contacting distance
 not greater than one inch.
- 47. A method as in claim 36 wherein:
 the container comprises a jacket defining an interstitial space positioned between

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the jacket and a wall of the container for receiving a flow of a cooling fluid said jacket further including a plurality of spiral baffles for enhancing thermal exchange between said fluid and said container.

- 48. A method as in claim 36 wherein: said medium is substantially uniformly heated or cooled.
- A method as in claim 36 wherein: **4**9. said medium is heated or cooled in substantially one direction relative to said structure.
- 50. A method as in claim 36 wherein: said heat exchange members are positioned to induce a thermal gradient in said medium such that said thermal gradient is in a predetermined direction.
- 51. A method as in claim 36 wherein: said medium is heated or cooled in a predetermined direction.
- 52. A method as in claim 36 wherein: said medium is heated or cooled such that the thermal gradient is in a predetermined direction.
- 53. A method as in claim 36 wherein: said medium is heated or cooled at a predetermined rate.
- A method as in claim 36 wherein: 54. said medium is heated or cooled such that the thermal gradient is in a predetermined direction and said heating or cooling occurs at a predetermined rate.
- 55. A method as in claim 36 wherein: said container has a nonporous bottom.



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- 56. A method as in claim 36 wherein: said container has nonporous walls.
- 57. A method as in claim 36 wherein: said container has a top.
- 58. A method as in claim 36 wherein: said container has a nonporous top.
- 59. A method as in claim 36 wherein: a portion of said first heat exchange member is configured to improve the thermal transport of said thermal transfer bridge.
- 60. A method as in claim 36 wherein: a portion of said second heat exchange member is configured to improve the thermal transport of said thermal transfer bridge.
- 61. A method as in claim 36 wherein:

 a portion of said first heat exchange member is configured to improve the thermal transport of said thermal transfer bridge and a portion of said second heat exchange member is configured to improve the thermal transport of said thermal transfer bridge.
- 62. A method as in claim 36 wherein: said second heat exchange member is placed at an end of said structure.
- 63. A method as in claim 36 wherein:

 a heat exchange fluid flows within the structure.
- 64. A method as in claim 36 wherein:

 a heat exchange fluid flows within the first heat exchange member.
- 65. A method as in claim 36 wherein:



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an interior portion of the first heat exchange member has baffles.

- 66. A method as in claim 36 wherein:

 the first heat exchange member is configured to maximize an area of a surface of the heat exchange member that is in contact with the medium.
- 67. A method as in claim 36 wherein:

 a heat exchange extension is at least partially coupled to the first heat exchange member.
- 68. A method as in claim 36 wherein:the biopharmaceutical product comprises proteins

REMARKS

Claims 1-20, and 22-35 have been cancelled. New claims 36-68 have been added. No new matter has been added thereby.

Rejections under 35 U.S.C. § 112:

The Office rejects claims 1-20, and 22-35 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants traverse this rejection.

First, Applicants point out that claims 1-20 and 22-35 have been cancelled, making moot their rejection. However, Applicants address the substantive nature of the rejections as they might be applied to newly added claims 36-68.

The Office suggests that "what is called a 'heat exchange member' in the claims is actually a 'fin' by disclosure. (Office Action at 2.) Applicants point out that the term heat exchange member is broader than just a fin, and can comprise additional structures, such as heat exchange extensions. Therefore, incorrectly terming heat

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